EXHIBIT HH

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Via Electronic Mail

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Re: In Re Pelvic Mesh/Gynecare Litigation - CT 291

Counsel:

Please accept this letter in response to Plaintiffs' request, through Jeff Grand, that Ethicon produce:

> "all product registries, their underlying data, and related documents (e.g., correspondence with investigators, emails concerning registries, contracts, etc.), including but not limited to:
>
> 1. TVT World
> 2. Prosima
> 3. TVT-Secur
> 4. TVT-O
> 5. Prolift +M"

Below is our understanding of the scope of the issue.

There are three ways in which it is possible that what you refer to as a "registry" may have been created: (1) as the result of a company-sponsorship; (2) as a result of an Investigator Initiated Study; or (3) independent of any involvement of Ethicon.

As we understand it, and interpreting your use of the term "registry" broadly in some instances to include reference items that we do not believe are registries, we are aware of the following:

I. COMPANY SPONSORED

A. **"TVT World"**

This is a registry that encompasses TVT, TVT-0 and TVT Secur, which was published as Tincello, Douglas, et als, "The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women," The Journal of Urology, Vol. 186, 2310-2315 (December 2011). The study bears the Ethicon number 300-06-006. It is our belief that we have produced the company information related to this registry with the various sources of Ethicon's clinical study productions. Specifically, this information is included with the productions of Ethicon's:

- US Trial Master hardcopy files
- UK hardcopy files
- UK TMF GroupShare
- EU Clinical Research Data Entry GroupShare

The productions in which these files can be located include: 12, 33, 36, 39, 43, 50, 54, 62, 70, 93, 95.

Additionally, a search of the documents produced reveals more than 26,000 documents that reference this study collected from other sources.

B. **A registry involving Prolift +M**.

We are aware of study entitled: GYNECARE PROLIFT+M™ Pelvic Floor Repair System WORLDWIDE OBSERVATIONAL REGISTRY, which bears the Ethicon number 300-08-004. We understand that information regarding this study was presented at the International Continence Society in 2011 and American Urogynecology Society in 2011. It is our belief that we have produced company information related to this study with the various sources of Ethicon's clinical study productions. Specifically, this information is included with the productions of Ethicon's:

- US Trial Master hardcopy files
- UK hardcopy files
- UK TMF GroupShare
- EU Clinical Research Data Entry GroupShare

The productions in which these files can be located include: 12, 33, 39, 43, 62, 93, 95.

Additionally, a search of the documents produced reveals almost 1,500 documents that reference this study collected from other sources.

C. **A registry regarding Prosima**.

We understand that data from a Prosima study was presented at the International Continence Society in 2011. This study bears the Ethicon number 300-07-011. It is our belief that we have produced the company information related to this study with Ethicon's clinical study productions. Specifically, this information is included with the productions of Ethicon's:

- US Trial Master hardcopy files
- UK hardcopy files
- UK TMF GroupShare
- EU Clinical Research Data Entry GroupShare
- Clinical Study Data

The productions in which these files can be located include: 12, 31, 33, 39, 43, 50, 54, 62, 70, 93, 95.

Additionally, a search of the documents produced reveals approximately 4,300 documents that reference this study collected from other sources.

II. INVESTIGATOR INITIATED ("IIS")

A. TVT-S (involving Dr. Lucente).

Plaintiffs previously informally requested this information. Jeff was going to provide me with some further details on the request, including the contract produced that identified its existence. We have inquired about this and learned that neither Dr. Lucente nor Dr. Murphy, nor anyone in their office at this time, knows if this information still exists or where it might be. Unfortunately, the individual at their office who was in charge of managing

information such as this was killed in an automobile accident a few weeks ago. The office is very upset and struggling to deal with this issue.

B. Prolift (involving Dr. Lucente)

Files from Dr. Lucente's Prolift IIS data were included in Production 100. This is not a registry.

C. **TVT Exact**.

Investigation has identified documents referencing an IIS bearing Ethicon's number 11-00-07-011) related to TVT Exact. We do not understand this study to be a registry. Moreover, this study has not started and there is no data available.

D. TVT, TVT-0 and TVT-S

Investigation has identified documents (produced) referencing an IIS for these products in which a Dr. Lobadasch was involved. This is an RCT and not a registry. Further, our investigation reveals that the study was closed after only a few patients were enrolled and there are no results reported of which Ethicon is aware.

III. INDEPENDENT

We are aware of a study by Collinet, Pierre, et als, "The Safety of the inside-out transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women," Int. Urogynecol J. (2008) 19:711-715. Investigation reveals that multiple copies of this study were produced in Ethicon's production documents. Our investigation to date indicates that Ethicon does not have data regarding this study. Further, our understanding from the published study itself that "Acknowledgements: Johnson & Johnson, France provided support for the electronic database and investigator meetings. All data analyses were independent of Johnson & Johnson."

Very truly yours,

Kelly S. Crawford/e
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